IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP. PELVIC SYSTEM PRODUCTS LIABILITY LITIGATION — **MDL NO. 2326**

THIS DOCUMENT RELATES TO:

ALL WAVE 3 CASES

PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY OF STEVEN SPIEGELBERG, PH.D. AND MEMORANDUM IN SUPPORT

Plaintiffs, pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby submit this Memorandum of Law in Support of their Motion to Exclude Certain Opinions and Testimony of Defendant's designated expert, Stephen Spiegelberg, Ph.D. ("Dr. Spiegelberg").

INTRODUCTION

Plaintiffs hereby seek to exclude certain expert testimony proffered by Defendant Boston Scientific Corp.'s ("BSC" or "Defendant") expert, Stephen Spiegelberg, Ph.D. ("Dr. Spiegelberg"). In support of their Motion, Plaintiffs state as follows:

This Court has previously ruled on the admissibility of many of the opinions expressed by Dr. Spiegelberg on behalf of BSC. *See, Tyree v. Boston Sci. Corp.*, Case 2:12-cv-08633, 2014 U.S. Dist. LEXIS 155138, *156-61 (S.D. W. Va. Oct. 29, 2014); *Frankum v. Boston Sci. Corp.*, Case 2:12-cv-00904, [Doc. 104], *64-67 (S.D.W.Va. May 1, 2015). Dr. Spiegelberg's report for Wave 3 of this litigation consists of his general causation opinions regarding the use of polypropylene in transvaginal mesh, and the opinions that he has formed after examining several explanted meshes from individual plaintiffs. With regard to his general causation opinions, Dr.

Spiegelberg's only addition to his previously ruled-upon report relates to the presence of black specs that were found in the mesh by Plaintiffs' expert, Dr. Russell Dunn. Accordingly, Plaintiffs will address his general causation opinions as briefly as possible in this motion. With regard to his specific causation opinions, Plaintiffs take issue with: (1) the cleansing/preparation protocol that he employed during his examination of the explanted mesh; and (2) the limitations of the techniques that he used to analyze the mesh. In the simplest sense, the methods he employed to examine those explants do not support his opinions and are unreliable. Finally, Plaintiffs seek to limit Dr. Spiegelberg's general causation opinions based on admissions that he made regarding what specific analytical measurement techniques can actually detect on explanted meshes.

LEGAL STANDARD

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence form which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: [E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony… is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry*, 178 F.3d at 261 and *Daubert*, 509 U.S. at 588,

595.) This Court "need not determine that the proffered expert testimony is irrefutable or certainly correct" – [a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Maryland Cas. Co.*, 137 F.3d at 783 (noting that [a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable and helpful").

Daubert mentioned specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."') (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert's* five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.... Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (internal citations and quotation marks omitted).

ARGUMENT

1. Dr. Spiegelberg's general causation opinions regarding the position statements of medical organizations should be excluded.

Dr. Spiegelberg, a chemical engineer, should not be allowed to characterize or otherwise refer to any position statements issued by medical professional societies because: (1) these opinions were not contained in his report; (2) he is not qualified to offer testimony on the topic; and (3) he lacks any reliable methodology in forming his opinions.

First, despite his willingness to offer opinions regarding the safety and effectiveness of BSC's products during his deposition in Waves 1 and 2, Dr. Spiegelberg did not include opinions relating to any position statements made by medical organizations in his current report. For that reason alone, this Court should find any opinions or testimony regarding position statements improper. Dr. Spiegelberg was not deposed as to his general opinions in Wave 3. Pursuant to Federal Rule of Civil Procedure ("F.R.C.P.") 26(a)(2)(B), an expert report must include "a complete statement of all opinions the witness will express and the basis and the reasons for them…." And courts have held that expert reports must be detailed enough to reflect the opinions an expert will offer on direct examination along with the reasons for those opinions. *See*, *Campbell v. U.S.*, 470 Fed. App'x 153, 156 (4th Cir. 2012) ("The expert report should be written in a manner that reflects the testimony the expert witness is expected to give at trial.") (quoting *Sharpe v. U.S.*,

230 F.R.D. 452, 458 (E.D.Va. 2005)). Because he failed to do so, any of Dr. Spiegelberg's opinions relating to these position statements should be excluded.

Moreover, as this Court has previously stated: "position statements are not expert opinions." *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *33 (S.D. W. Va. Jul. 8, 2014). Since Dr. Spiegelberg is not using his own "scientific, technical, or other specialized knowledge" to conclude that these positional statements have merit, he should not be allowed to testify regarding them. *See*, Fed. R. Evid. 702.

2. As this Court previously ruled, Dr. Spiegelberg's state of mind, intent, and "scientific validity" opinions related to Material Safety Data Sheets (MSDS) should be excluded.

Dr. Spiegelberg seeks to tell the jury that there is no scientific evidence to support the plain language of the MSDS for the polypropylene resin used in the relevant devices. At issue is the warning added to the MSDS by Chevron Phillips, the manufacturer of the Marlex resin used in BSC's polypropylene mesh products, that reads: "MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." (*See*, MSDS, as attached hereto as Exhibit 1, at 1). As he has previously done, Dr. Spiegelberg seeks to offer the opinion that there is no scientific validity for that warning—which he instead attributes to Chevron Phillips' fear of liability. But, Dr. Spiegelberg still has no support for his "infer[ence] that Chevron Phillips lacked a scientific basis for adding the warning." (See, Spiegelberg Report, as attached hereto as Exhibit 2, at 40-42); *Tyree*, 2014 U.S. Dist. LEXIS 155138 at *158-61. As this Court previously ruled, Dr. Spiegelberg should not be permitted to speculate regarding the scientific validity of this warning because "Chevron Phillips's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and

ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Id*. Accordingly, these opinions should not be allowed at trial.

3. Dr. Spiegelberg is not qualified to opine on any matters related to the FDA clearance process (or BSC's compliance with it).

Dr. Spiegelberg spends several pages of his report discussing FDA requirements, BSC's compliance with these requirements, the FDA's intent or state of mind with regard to BSC's products and conduct, and certain FDA design control standards that he asserts were followed by BSC. *See* Exhibit 2 at pp. 5, 10, 15, 16, 31-41. Dr. Spiegelberg is not a regulatory expert and is not qualified to discuss FDA regulations, the FDA 510(k) clearance process, the significance of 510(k) clearance, or BSC's actions or compliance with respect to the FDA. *See,* Dr. Spiegelberg CV, as attached hereto as Exhibit 3. Moreover, even if Dr. Spiegelberg did possess the requisite qualifications, as briefed many times to this Court, any such testimony should be excluded as irrelevant under Federal Rules of Evidence 402 and 403. *Tyree,* 2014 U.S. Dist. LEXIS 155138 at *168-69.

4. Dr. Spiegelberg's opinions regarding the presence of black specks in BSC's mesh are unfounded and unreliable.

Dr. Spiegelberg also seeks to opine that the black specks seen in exemplar BSC meshes were only reflections of light, rather than contaminants. *See,* Exhibit 2 at p. 12. Plaintiffs' expert, Dr. Dunn, described the presence of black specks in his expert report as follows:

> Significant debris (black specks) was observed throughout the polypropylene monofilament fibers for all BSC products. Black specks are small areas of highly degraded polymer that have been carbonized due to excessive residence time in an extruder. Black specks are also referred to as 'burnt resin' and are a contaminant in the polymer monofilament.

See, Dr. Dunn expert report at p. 19, as attached hereto as Exhibit 4. In response, Dr. Spiegelberg conducted his own examination—which consisted of him unraveling a piece of polyform mesh

and then turning the monofilaments in the light, such that, at certain angles, the black specks were not visible to him. *See*, Dr. Spiegelberg Deposition, at pp. 18-24, as attached hereto as Exhibit 5. He also testified that the black specks were only apparent in the curvature of the mesh and did not appear in areas that had been left straight during the knitting process. However, Dr. Spiegelberg did not even bother to review the photos supplied by Dr. Dunn to confirm that the black specks were only apparent in the curves of the meshes he examined. *Id*. at 27:6-14. Had Dr. Spiegelberg done so, he would have seen that black specks are apparent in both the straight areas and in the curved areas of BSC's mesh. *See*, Dr. Dunn's examination of the Uphold device, photo MDP E011, as attached hereto as Exhibit 6. Further, Dr. Spiegelberg no longer has the mesh that he unraveled, has no photographs from his examination, and therefore bases his opinion solely on what he claims he saw. *Id*. These findings are completely unreliable and not-reproducible, and Dr. Spiegelberg has provided no evidence to Plaintiffs' counsel to support his opinions in this regard. Accordingly, this testimony should not be allowed at trial. *See*, Fed. R. Evid. 702.

5. Dr. Spiegelberg's opinions regarding individual Plaintiffs' meshes should be excluded because his methodology is unreliable and will not help a trier of fact.

Dr. Spiegelberg's self-created protocol for preparing and examining explanted mesh does not comport with the scientific method. First, his preparation/cleaning of these meshes was not designed to preserve evidence of any oxidized polypropylene that may have been apparent on the surface of these explants. *See*, Ex. 7, Spiegelberg Suppl. Rpt. Second, the methods he chose to examine these meshes involved irregularities in their technique and analysis. As a result, any conclusions Dr. Spiegelberg drew from the data he collected cannot be considered reliable and should be excluded.

a. The protocol for preparing explanted meshes could have destroyed evidence of oxidized polypropylene.

Dr. Spiegelberg's protocol for preparing and cleaning the explanted mesh (the "Protocol") was developed by Dr. Spiegelberg, himself. *See*, Exhibit 5 at 68:24-70:3. Dr. Spiegelberg first soaked the explants in a potassium hydroxide solution for a week; the purpose of this step was to dissolve any collagen or protein that was in contact with the surface of the explanted mesh. *Id*. at 136:2-138:9. However, while Dr. Spiegelberg testified that the potassium hydroxide will not react with polypropylene, he did not know—nor had he investigated—if this potassium hydroxide soak created free radicals when it dissolved tissue/protein. *Id*. This is an important oversight, because if this step did create reactive species, they could react with any oxidized polypropylene on the mesh's surface. As such, this oversight created the potential for the destruction of Plaintiffs' evidence. Calling this destruction "unlikely" and "doubtful," Dr. Spiegelberg testified that he could have researched this potential problem, but he simply chose not to do so. *Id*.

In addition, the Protocol also included soaking the explanted samples in a bath of hexane; the purpose of this step was to leach out any fatty acids that *may* have been absorbed by the mesh. *Id.* at 55:23-57:1. However, Dr. Spiegelberg could not name a single peer-reviewed publication that concluded that fatty acids *are* absorbed by implanted polypropylene mesh. *Id*. What is worse, Dr. Spiegelberg did not know if this hexane bath would leach antioxidants out of the mesh—or if the leaching of these compounds would create reactive species that could destroy plaintiffs' evidence of oxidation. *Id*. at 99:23-100:5. Dr. Spiegelberg admitted that the antioxidants in the explanted samples would be altered in the presence of free radicals. *Id*. at 135:23-136:15. And while he testified that the hexane does not react with polypropylene, he did not know if hexane reacted with any tissue or enzymes that were associated with explanted samples. *Id*. at 50:6-51:15.

The two steps described above were performed on every mesh Dr. Spiegelberg examined. Therefore, all of his observations based upon these samples are scientifically unreliable. Simply put, proper care was not taken to understand or prevent the destruction of evidence in Plaintiffs' explanted samples. As such, Dr. Spiegelberg could not possibly tell a jury that his protocol did not destroy evidence of oxidation—the very thing that he claims he was looking for. As a chemical engineer with knowledge of human tissue and the complex chemical reactions occurring in the body, Dr. Spiegelberg should have taken the proper care in this protocol, but he did not. His failure to do so should provide a basis to exclude his opinions based upon this testing.

b. The analyses performed were significantly limited.

Dr. Spiegelberg's instrumental analyses varied from mesh to mesh. First, he performed an assessment on the compliance of the meshes after they were cleaned by comparing them to the relative compliance of a mesh that had never been implanted. In every case, he concluded that the cleaned explanted mesh was as complaint as the never implanted mesh. This assessment of mesh compliance was made based solely on observations that he garnered while handling each mesh with tweezers—no pull testing, break strength, elongation, or any other standardized testing was performed and no data was collected. *Id*. at 173:14-23. Since this "compliance assessment" was based merely on Dr. Spiegelberg's own personal observations and opinions, the comparison he made was subjective in nature and is not repeatable or scientifically reliable. As such, it would not be helpful or appropriate for a jury.

After assessing its compliance, Dr. Spiegelberg then performed an FTIR analysis of the mesh. Next, he took SEM photographs of the samples. If he saw cracks in the mesh in the SEM photographs, he would perform an EDS analysis on an area he selected from the cracked region in order to determine what elements were present in the cracks. If cracks were not seen, however, no

EDS analysis was performed. Each of these analyses (FTIR, SEM, and EDS) has different limitations and can provide different data to the end user; however, while Dr. Spiegelberg was aware of these limitations, did not acknowledge them in his case-specific opinions.

First, Dr. Spiegelberg testified that his FTIR measurements could not detect antioxidants in the mesh because they are at such low concentrations. *Id*. at 103:7-11. This admission infers that anything at similarly low concentrations, including oxidized polypropylene, will not be picked up by the FTIR either. Further, Dr. Spiegelberg testified that his FTIR measurements were taken randomly—determined by his ability to get a signal—and that the entire sample was not examined. *Id*. 200:21-201:2. He added that his FTIR readings would have been clearer if he had performed a baseline correction for each mesh that he examined; stating that the baseline correction "wouldn't have changed my opinion. It's just it would be -- for someone who doesn't look at FTIR on a daily basis, it would be absolutely clear to you." *Id*. at 120:22-121:1. Taken together, these limitations of the FTIR scans add significant insight into the opinions that Dr. Spiegelberg is proffering here.

Similarly, SEM images were only captured by Dr. Spiegelberg of representative areas of each sample—and he did not perform an EDS analysis unless he observed cracks on the surface of the mesh. *See, Id*. at 67:2-69:3. Dr. Spiegelberg testified that EDS was only performed to ascertain the elemental composition of the cracked regions and, importantly, that this analysis cannot confirm or rule out the presence of oxidized polypropylene when oxygen is one of the elements found in those cracks. *See, Id*. at 285:21-287:1. Moreover, Dr. Spiegelberg testified that the Protocol used "an abundance of hexane," such that, if any fatty acids had been absorbed *in vivo*, they would have been removed during this hexane bath. *See, Id*. at 55:12-56:6. Yet, every time his FTIR or EDS analyses showed evidence that could be mesh oxidation, his explanation was that the hexane soak must not have removed all of the fatty acids that were absorbed. *See, Id.*

at 55:12-56:6; 277:3-14. Given these limitations, the case-specific opinions offered will not aid a trier of fact and instead will only confuse the issues present.

c. The opinions offered regarding the individual Plaintiffs are not scientifically reliable.

When considering the contradictory nature of the opinions offered, it is clear that Dr. Spiegelberg is actually relying more on his purported experience and knowledge, rather than his examination of these meshes—and that he is actually attempting to proffer his general causation opinions disguised as case-specific ones. Dr. Spiegelberg admitted that FTIR cannot measure antioxidants in these meshes because they are at low concentrations—meaning that oxidized polypropylene at similar levels on these meshes would not register either. Yet, Dr. Spiegelberg seeks to opine, in every case, that no oxidation has taken place on the mesh that he examined. And he also testified that whenever he saw evidence that could be attributed to oxidized polypropylene, he instead attributed it to the presence of fatty acids or biologic material remaining in the sample—even though his protocol was specifically designed to remove biologic material and pull fatty acids out of these samples. Given these inconsistencies, Dr. Spiegelberg should not be allowed to tell a finder of fact that any individual plaintiff's mesh was not oxidized. In sum, his Protocol could have destroyed evidence of oxidation and his conclusions are contradictory in nature and unscientific—these flaws cannot be undone, and no jury should hear about this testing.

6. Dr. Spiegelberg's general causation opinions should also be limited based on his admissions regarding the usefulness of FTIR and EDS.

Finally, Dr. Spiegelberg's general causation opinions should be limited based on his admissions regarding the data that can be reasonably extrapolated using FTIR and EDS techniques. For the reasons outlined in the section above, Dr. Spiegelberg should be prevented from making sweeping statements regarding any lack of evidence—either in peer-reviewed literature or from

his own examinations—to indicate that polypropylene mesh oxidizes *in vivo*, when those opinions are based on FTIR or EDS results, alone. While his admissions regarding the limitations of these techniques may also be grounds for cross-examination, the fact remains that any generalized statements or opinions regarding the purported lack of evidence of oxidation, without qualification or explanation of the limitations inherent to these techniques, will only mislead or confuse the jury.

Date: January 11, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: */s/ Aimee H. Wagstaff*
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